Response to FDA Unique Device Identifier (UDI) Request for Comments Docket Number FDA-2008-N-0661

Alcon Laboratories, Inc. appreciates the opportunity to provide the following feedback and comments on the FDA's Unique Device Identifier (UDI) Questionnaire. We commend the FDA direction to seek wide input from a variety of stakeholders to assist in defining a common direction for UDI, and we especially appreciate the leadership in bringing together numerous regulatory agencies to work towards common global solutions.

Alcon Laboratories, Inc. is the world's premier eye care company, with leading positions in Pharmaceuticals, Medical Devices, and Consumer Products.
In the Medical Device area specifically, we manufacture and distribute a wide array of products and technologies including:

- Low-technology consumables
    - Surgical drapes, wound dressings, syringes, sutures
    - Contact lens care storage, disinfection, re-wetting
- Medium technology medical devices
    - Precision disposable surgical instruments
    - Ophthalmic Viscoelastic Devices
- High-technology products such as
    - Precision re-usable ophthalmic surgical instruments
    - Implantable intraocular lenses and associated delivery systems
    - Surgical consoles containing software, lasers, advanced fluidics, and other features supporting cataract, vitreoretinal, and refractive surgical procedures

Alcon is uniquely positioned to comment on this questionnaire from a number of perspectives:

- We are one of a few companies providing Pharmaceuticals, Medical Devices, and Consumer Products to the global marketplace
    - We operate in over 75 countries with sales of over $6 billion USD and work every day in a truly global environment
- We have deep knowledge covering a wide variety of medical devices which are sold in numerous supply chain channels
- We have over 30 years of experience with AIDC marking using both GS1 and HIBCC standards

- We actively lead industry and standards teams charged with defining standards and guiding implementation of solutions related to UDI, Track/Trace, Anti-Counterfeiting, and related areas

As current Co-Chair of the GS1 Healthcare AIDC Application Standards Workteam and a member of the GS1 Healthcare Leadership Team, Alcon Laboratories, Inc. ***strongly supports and recommends the adoption and use of GS1 standards to support this global UDI initiative***.

The solutions being finalized under the GS1 Healthcare initiative are the only global set of holistic solutions available today that address all 3 key portions of a potential UDI solution:

GS1 AIDC Standards

- GS1 is the leading source of AIDC standards used by over 1 million member companies in virtually every country in the world, and enables over 5 billion AIDC-assisted transactions per day
- GS1 Healthcare has completed the standards for the AIDC data carrier and the data required for every type of healthcare item at every packaging level
- Currently in the 'Global Standards Management Process' (GSMP) for cross-industry approval

GS1 GDSN Standards (Global Data Synchronization Network)

- GDSN is a set of standards with supporting software systems *in use today* to exchange product data between trading partners
- GS1 Healthcare has completed the extensions of the existing standards and systems to more completely support the specialized needs of healthcare products
- Currently in the 'Global Standards Management Process' (GSMP) for cross-industry approval

GS1 Traceability Standard

- A set of standards defining the messaging protocols and associated data and information requirements to support end-to-end traceability
- GS1 Healthcare has completed the extensions of the existing standards and systems to more completely support the specialized needs of healthcare products
- Currently in the 'Global Standards Management Process' (GSMP) for cross-industry approval

The HIBCC system, although in use today, has 4 key problems when positioned as a candidate for a global UDI compliance solution:

- The HIBCC system is mainly a US-deployed system, with a small number of other countries only minimally deployed
- Even within the US, HIBCC usage is predominantly within the hospital community, not widespread throughout the remainder of the supply and dispensing chain
- The HIBCC system does not provide a solution or standards regarding traceability; it only addresses the AIDC marking, and to a very limited extent the product catalog needs
- Finally, the number of data carriers supported by HIBCC falls well short of the number of data carriers supported by GS1. There is no standard within HIBCC for RFID and other non-line of sight technologies (although there is a technical advisory, there is no standard and there is virtually no adoption of RFID using the HIBCC advisory).

After review of this UDI Questionnaire, we believe that FDA should consider additional clarification and focus on the following topics:

- Defining whether the UDI database is intended to be an end-to-end track/trace system, an authentication system, a pedigree system, a repository of static product data, or something else. It is not clear what the intended use or future direction is based on the survey questions.
- If the UDI system is not intended to track/trace product movements, then the desire to have products carrying Lot and/or Serial Numbers in AIDC should be seriously reconsidered. There is little to no value in providing AIDC marking of these attributes unless the marks will be used by the supply and dispensing

chain participants, and it is unlikely that the marks will be used unless there is a requirement to track/trace movements.

- The very real need for exemptions and/or waivers to compliance for some categories of medical devices, and for specific medical devices

In closing, we further encourage FDA to include phased implementation as part of the overall regulatory solution. For instance, there are many medical devices that are relatively easy to apply AIDC marks and UDI information onto, and these can facilitate early successes across a broad range of the market. The more challenging and exceptional products should be granted exemptions and waivers until later phases of the implementation. This affords 2 distinct benefits:

- Attention is focused on the 80-90% of the products that can be marked, without having to deal with the distractions and timeline delays of resolving the 10-20% exceptions
- It provides time and incentives for the technology to improve so that the remaining small percentage of products can be more effectively addressed

We look forward to continued collaboration with the FDA on this important initiative, and stand ready to offer our expertise and continued assistance in defining global solutions to UDI.

Response to FDA Unique Device Identifier (UDI) Request for Comments Docket Number FDA-2008-N-0661

Section B: Questions Pertaining to the UDI System

1. Which types of devices or particular devices should be subject to the requirements of a UDI system? Which types of devices or particular devices should be excepted?

Section 519(f) of the act states that the Secretary of Health and Human Services may provide ``an exception for a particular device or type of device'' however, the statute does not specify any criteria for an exception, nor does it describe the scope of an exception.

a. Should all devices be subject to the requirements of a UDI system? Please explain your reasoning.

- **Alcon Response:**

"Unique identification" consists of 2 separate concepts:

1. Product Data: a code that identifies the Manufacturer + the product model or style (differentiates this manufacturer's product from all others).
2. Production Data: specific information about the Lot and/or Serial Number, which identifies increasingly granular instances of individual lots and/or unique items. This may also be associated with Expiry Date.

In order to determine whether specific devices should be subject to the requirements of the UDI system - one must consider the different levels of the UDI and their application:

1- Assigning a UDI with Product Data only: a number for example can be assigned to all devices and registered in a database

2- Applying the UDI to the package: considerations are inner package, outer package, each level, pack level, carton level - will vary depending upon size, feasibility, practicality, cost, usage, and benefit to the end user.

3- Applying the UDI directly on the product: considerations are feasibility, size, material, cost of mfg, biocompatibility, revalidation, business need, usage, and benefit to the end user.

4- Production Data beyond the UDI number-- what other data elements are required and at what packaging levels are they required.

We believe that the FDA should consider a risk-based, phased-in approach to the UDI requirements for Product Data and especially for Production Data, for those

elements of UDI that are intended to be marked onto the packaging and/or the physical product.

b. Are there types of devices or particular devices that should receive an exception from the requirements of a UDI system? If so, what types of devices or particular devices should receive an exception and why?

- **Alcon Response:**

  At minimum, the following classes of devices should be exempted from the UDI requirements, at least in the initial phases until further study can be completed. There are complex issues surrounding each of these categories and industry consensus is lacking.

  --Kits

  --Combination Device / Drug

  --Custom Devices made for a specific person

  --Very small surgical instruments for Ophthalmic and Neurosurgical procedures

  --For Capital Equipment: Service parts, spare parts, accessories

  In addition to exclusion of these general classes of devices, we highly recommend that a formal Exemption or Waiver process be incorporated into the final regulation, similar to that in the FDA Barcode Regulation for Pharma, whereby manufacturers can request exemptions for specific devices based on facts submitted.

Response to FDA Unique Device Identifier (UDI) Request for Comments Docket Number FDA-2008-N-0661

2. What are the characteristics or aspects necessary to uniquely identify a device?

Section 519(f) of the act states that the UDI ``shall adequately identify the device through distribution and use, and may include information on the lot or serial number.'' The statutory language does not describe the characteristics or features that make a device``unique'' or that ``adequately identify the device through distribution and use.''

a. What characteristics are needed to uniquely identify a device?

- **Alcon Response:**

  "Unique identification" consists of 2 separate concepts:

  1. Product Data: a code that identifies the Manufacturer + the product model or style (differentiates this manufacturer's product from all others)

  2. Production Data: specific information about the Lot and/or Serial Number, which identifies increasingly granular instances of individual lots and/or unique items. This may also be associated with Expiry Date.

  Application of Production Data should be based on product risk to patient safety, current regulatory requirements, and balanced vs. costs to implement to assure the continued availability of affordable treatments.

b. What core attributes, elements, or characteristics of a device should constitute a minimum data set for a device identifier?

- **Alcon Response:**

  Product Data:

  - Applies to all in-scope devices.
  - Minimum requirement is to input the UDI number into the database and to mark the UDI in human-readable format on the packaging.
  - Product markings to carry the Product Data UDI in barcodes or other automation should be based on product risk and phase-in schedule.

  Production Data:

  - For selected in-scope devices only, based on risk and phase-in schedule.
  - Minimum requirement for in-scope devices is to mark the Production Data in human-readable formation on the packaging.
  - Product markings to carry the Production Data UDI in barcodes or other automation should be based on product risk and phase-in schedule.

c. What changes to an attribute, element, or characteristic associated with the unique identification of a device change should result in a new UDI?

- **Alcon Response:**

  Typically, changes to fit, form, or function may result in the need for a UDI change. The decision is best left to the manufacturer using healthcare sector standards and industry best practices such as the GS1 GTIN Allocation Rules for Healthcare.

d. Should the UDI include a component that represents package size or packaging level?

- **Alcon Response:**
  - Both the HIBCC and GS1 systems have mechanisms for associating the UDI (which is different for each packaging level in those schemes) with stored master data in an electronic database--this stored information can include relevant information such as package size, unit of measure, packaging level definition, number of units in that packaging level, etc.

  - The key concept: the UDI alone does not carry full definition of packaging level--it is a pointer to a database record containing that information.

e. To what extent would or should the list of unique device characteristics vary depending on the type of device?

- **Alcon Response:**
  - The Production Data requirements (Serial Number, Lot, or no control) should be based on product risk, follow the practices and/or regulations now in place for medical devices and their accessories, and balanced against the costs to implement and deploy across the entire supply chain.

  - Additionally, there is little value in a UDI that carries additional Production Data unless a significant number of supply and treatment chain partners are willing and able to adopt and use that information. FDA mandated requirements should consider this in their rulemaking.

3. What should be the UDI's components?

a. Could existing standards, such as the standards used by GS1, Health Industry Business Communications Council (HIBCC), or others be used as a model for the UDI system? What are the advantages and disadvantages of these existing organizations and standards?

- **Alcon Response:**
  - Yes, existing standards should be used. We strongly support the use of existing GLOBAL industry standards. We would therefore strongly discourage the creation of new standards.

  - Alcon prefers a solution based on the GS1 set of standards.
    a. The HIBCC system, although in use today, has 3 key problems when positioned as a candidate for a UDI compliance solution:
       i. The HIBCC system is mainly a US-deployed system, with a small number of other countries only minimally deployed
       ii. Even within the US, HIBCC usage is predominantly within the hospital / provider community, not widespread throughout the remainder of the supply and dispensing chain
       iii. Finally, the number of data carriers supported by HIBCC falls well short of the number of data carriers supported by GS1. There is no standard within HIBCC for RFID and other non-line of sight technologies (although there is a technical advisory, there is no standard and there is virtually no adoption of RFID using the HIBCC advisory).

Advantages of the GS1 system:
-standards are in-place (or being finalized) and ready for quick adoption.
-global, open usage of these standards across many sectors.
-strong penetration in Retail, where many Healthcare items are sold.

Disadvantages:
-use of the standards requires a minimal financial commitment

b. Some identification systems currently in use employ a combination of a device identifier (meaning information that identifies the manufacturer, make, and/or model of the device) and a production identifier (meaning information that relates to the lot or serial number). What should the device ``identifier'' component of the UDI cover or contain?

- **Alcon Response:**
  - The 'Product Data' portion of the UDI should contain, at minimum:
    a. a code identifying the Manufacturer / Brand Owner, and
    b. a code identifying the make / model / style of the product.

c. With respect to the production identifier, we note that the statute says that the UDI may include information on the device's lot or serial number. When should lot or serial number information be required for a device? Are there particular devices for which serial numbers should be required? If yes, what particular devices should be labeled with a serial number? Please explain your reasoning.

- **Alcon Response:**
  - Lot and Serial Number should be applied using the following rationale:
    a. based on product risk to the patient
    b. based on current regulatory requirements and industry practices (i.e., these attributes should only be applied when there is a current regulatory requirement, and should not be extended to other product types where there is not a corresponding requirement)
    c. balanced vs. the costs to implement and the subsequent impact on affordability of healthcare treatments

d. How might we ensure that UDIs, regardless of the manufacturers or devices associated with those UDIs, are uniform or standardized in their structure or composition? For example, the NDC (National Drug Code) number is always 10 digits long and always presents the labeler code first, followed by the product code and then the package code. Should we limit the number of ways that the UDI can be created or the standards to be used?

- **Alcon Response:**
  - Use of existing GS1 and HIBCC global standards assures that UDI's are consistent, globally unique, and structured in a common format for consistent and reliable decoding by trading partners.
  - The UDI should be limited to the GS1 system standards or the HIBCC system standards.
  - Only the GS1 system of standards guarantees true global uniqueness across all affected healthcare sectors (including Retail, Hospital, Distributor, Home Health Care)--the HIBCC standards only address a select number of countries with a focus on the Hospital / Provider sector.

e. How should the UDI be created to ensure that UDIs are unique?

- **Alcon Response:**
  - Using the current GS1 GTIN Allocation Rules assures global uniqueness of UDI's.

4. Where should the UDI be placed? What should be the criteria for alternative placement of the UDI?

The statute requires the label of devices to bear a unique identifier, unless we require an ``alternative placement'' or provide an exception. Section 201(k) of the act defines ``label'' ``as a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the [[Page 2603]] outside container or

wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.'‘

a. Should we specify where on the label the UDI must appear? If so, where should the UDI appear on the label? Please explain your reasoning.
   - **Alcon Response:**
     - No. The variety of packaging form factors make such mandatory placement guidance overly complex and impossible to implement. The placement should be determined by the manufacturer / brand owner based on the unique characteristics of the device, intended use, supply chain trading partner requirements, GS1 and HIBCC standards, and other considerations.

   i. Should we allow the components of the UDI to be placed separately on the same package or on different levels of packaging? For example, if the UDI consists of a device identifier component and a production identifier component, should we allow the device identifier component of the UDI to be placed in one location and allow the production identifier component to be placed elsewhere on the label or on the device? Please explain your reasoning.

   As another example, some devices are packaged individually and then packaged again in a larger container (such as a ``shelf pack''). We are aware that some manufacturers would prefer placing both the device identifier component of the UDI and the production identifier component of the UDI on the larger container and placing only the device identifier component of the UDI on the individual packages. Separating UDI components or allowing part (rather than all) of the UDI on package labels may provide for flexibility in product labeling, but also generate confusion as to which UDI to read or scan (if the UDI components are separated) or limit the usefulness of the UDI if a component of the UDI is not present.
   - **Alcon Response:**
     - The number of barcodes and/or tags should be applied in conformance with the GS1 Healthcare AIDC Application Standards Workteam standards to support the intended use of the product. This standard defines when it is necessary or desirable to have more than one AIDC

marking on a product, while striving towards only one AIDC mark per packaging level. This also leverages GS1 rules regarding whether the information should be concatenated into a single barcode or split into 2 or more barcodes.

- For example, a medical device (or pharmaceutical) that is sold in both retail and hospital settings may require at least 2 barcodes to meet the needs of these very different stakeholders—a UPC or EAN code may be needed to enable point-of-sale scanning to support retail users, while potentially coexisting with a GS1-128 or Data Matrix barcode containing extended information to support hospital or provider users.

ii. For barcodes (whether linear or two-dimensional (2D)), should we require the UDI to be expressed in a concatenated manner (whereby the components of the UDI are expressed on the same line adjacent to each other) or in a stacked manner (whereby one component of the UDI rests atop the other component)?

- **Alcon Response:**
  - FDA should mandate that UDI's conform to the GS1 or HIBCC system standards, which clearly define the rules for when symbols can be concatenated, and if not concatenated, rules for ensuring reliable readability and placement of the symbols.

  - FDA should not dictate specifics beyond the standards, such as adjacent or stacked placement, due to the vast variety of product sizes, configurations, packaging constraints, etc. Decisions regarding symbol construction, placement, and application should be left to the manufacturer / brand owner, who is in the best position to make these complex trade-off assessments.

  - The GS1 Healthcare AIDC Application Standard workteam standards address this issue in sufficient detail to avoid the need for additional regulatory guidance.

b. Are there devices where we should require the UDI to appear on the device itself (direct part marking)? For example, it might be beneficial to put the UDI on the device itself if the device is re-processed because this might help firms identify or record how many times a particular device has been reprocessed. Similarly, certain single use devices (SUDs) sometimes are reprocessed, so a UDI on the device itself could facilitate the mandatory and voluntary MedWatch reporting relating to such reprocessed devices or facilitate other activities (such as documenting sterilization reprocessing of SUDs and validation studies) associated with SUDs. Conversely, are there devices where the UDI cannot or should not go on the device itself? If so, please describe those devices and explain why the UDI cannot or should not go on the device.

- **Alcon Response:**
  - Multi patient reprocessed surgical instruments should require direct part marks, whenever this is technically feasible.
  - Note that some instruments will be technically infeasible to mark with current technology, and the FDA should allow the manufacturer / brand owner to request specific exemptions for these products until such time that technology becomes available to mark those products.
  - The GS1 Healthcare AIDC Application Standard workteam standards address this issue in sufficient detail to avoid the need for additional regulatory guidance.
  - If SUD are reprocessed, a new UDI identifying the reprocessor should replace the original UDI of the manufacturer / brand owner.
  - The following general classes of products should not be subject to direct part mark requirements:
    a. implants of any kind, to prevent biocompatibility and other issues
    b. very small surgical instruments such as those used in Ophthalmology or Neurosurgery, where the curvature radius and/or small size will not permit direct part marks using currently available technology

c. If we allow for “alternative placement" of the UDI for some particular devices or types of devices, what should be the general criteria for requiring “alternative placement" of the UDI, e.g., such as on the device itself or other location that is not on the label?

- **Alcon Response:**
  - FDA should allow alternative placement at the manufacturer / brand owner discretion. This would enable potentially more items to be marked without the need for creating and enforcing complex guidance in this area.

d. What specific challenges or limitations exist regarding “alternative placement?" For example, placing a UDI in an automatic identification form on an implantable device may present issues as to whether the automatic identification technology affects the device's integrity or function. As another example, certain devices, such as software, may pose particular challenges for how to label with a UDI.

- **Alcon Response:**
  - See previous answers above.

5. How should the UDI be presented?

We are aware of several automatic identification technologies in use, such as linear bar codes, 2D bar codes, and radio frequency identification. We also note that various FDA regulations and initiatives have required or recommended one or more automatic identification technologies (see 21 CFR 201.25 (bar code label requirement for human drug products); 21 CFR 610.67 (bar code label requirement for biological products); Ref. 2; and section 505D of the act (21 U.S.C. 355e) (regarding ``pharmaceutical security" and specifying ``promising technologies" such as RFID (radio-frequency identification), nanotechnology, encryption technologies, and other ``track-and-trace or authentication technologies")). Therefore:

a. Should we require human-readable UDIs or automatic identification of UDIs or both? Are there devices where it would be sufficient to have human-readable UDIs alone? Please explain your reasoning. For example, devices used in a home care setting might not need an automatic identification UDI because the home might not be equipped to read the automatic identifier. Are there situations where we should require both human-readable and automatic identification UDIs? Please explain your reasoning.

- **Alcon Response:**
  - See Answer 2.b above.
  - Where space is not available, the human readable can be suppressed using industry guidance such as that contained in the GS1 Healthcare AIDC Application Standards.
  - FDA should also consider what other UDI information is currently printed on the product or label to assure unique identification consistent with Agency objectives. For instance, the Lot, Expiry, and/or Serial Number may already be printed onto the product to meet regulatory requirements--if so, requirements to print human-readable UDI information associated with barcodes or other technology should not be in addition to this already-required text.

b. Should we specify a particular type of automatic identification technology or should we allow the automatic identification technology to vary depending on the type of device? Should we identify automatic identification standards (as opposed to specific technologies) that can be used? Please explain your reasoning. Specifying a particular type of automatic identification technology would enable hospitals and other parties who might read or use a UDI to make specific investments in scanning or reading equipment, but the technology chosen might not be easily applied to all devices (if we require the UDI to be placed somewhere other than the label.) For this question, we are particularly interested in hearing from parties who might use UDIs as well as entities that may have already adopted or installed device identification systems.

- **Alcon Response:**
  - We recommend that the Agency simply require compliance to existing industry standards such as GS1 set of standards, and allow ANY of the available technologies within those standards to be applied at the manufacturer / brand owner discretion.

- We believe that the GS1 AIDC Application Standards Workteam standards represent the optimal balance between standardized markings / standardized data, and the flexibility to choose alternative AIDC data carriers to solve challenging marking problems.
- There are many different AIDC data carriers in existence for one good reason—each brings specific strengths to bear in solving challenging marking problems. The GS1 AIDC Application Standards Workteam standards represent a multi-discipline solution to marking the maximum number of products with the maximum level of standardization.
- The standards bodies routinely ensure forward and backward compatibility as part of the new technology introduction process while providing flexibility to adopt new technologies as they are developed, without need for constant regulatory changes every time a new technology is developed.

c. Should we allow the use of different automatic identification technologies to express different parts of the UDI? For example, the device identifier component might be expressed in a linear bar code and the production identifier component might be expressed in a 2D bar code. Allowing the use of different technologies for different components of the UDI may enable manufacturers to make more efficient use of label space or space on the device itself, but it also could generate confusion as to which identifier to read or scan and could necessitate the purchase of several types of reading and scanning equipment.

- **Alcon Response:**
  - See Answer 4.a.i.
  - We believe that the GS1 Healthcare AIDC Application Standards Workteam has developed recommendations working across all segments of the supply chain that balance the need for flexibility in choice of data carrier with the need for standardization.

d. Are there existing standards or systems we should consider in establishing the requirements for how the UDI must be presented? For example, we are aware of various standards organizations, such as GS1 and the HIBCC, that exist and have specific formats or specifications for automatic identifiers for products. Should we allow any or all of these standards to be used?

- **Alcon Response:**
  - FDA should allow either the GS1 or HIBCC set of standards. We are unaware of any other standards that meet the requirements for a UDI system.

6. How should the UDI Database be developed and maintained?

For parties to benefit from UDI information, it would seem necessary for those parties to know, at a minimum, the UDIs that exist, the specific device associated with each UDI, and the information associated with each UDI. It might be efficient for one entity to collect the UDIs, associate those UDIs with specific devices, and make the information associated with those UDIs publicly available. However, it is also conceivable (but perhaps less efficient or more costly) that the information could rest with individual manufacturers themselves (rather than FDA) or with a third party or third parties. Consequently:

a. How and when should we require UDIs and associated information to be entered into a database? How frequently should we require changes to a UDI or to the information associated with or linked to a UDI to be reported?

- **Alcon Response:**
  - Recommend a phased-in, scaled approach to implementation for both product markings and input into the database over a 5-7 year timeframe.
  - New product introduced to market after effective date of the regulation should be compliant (input into the database, and marked on the products as applicable based on risk) at time of product launch.
  - Products introduced prior to the effective date of the regulation should be allowed 5-7 years to become compliant (input into the database, and marked on the products as applicable based on risk) since significant operational changes,

packaging changes, re-registrations in other countries, ISO CE Mark dossier updates, and other time-consuming work will be required to retrofit those products.

- Database Updates: The manufacturer or brand owner should make changes to the database in a timely manner upon every change to the device requiring a database change. Determining when a database change is needed should be guided by industry standards such as the GS1 Healthcare GTIN Allocation Rules.

b. Aside from information that is necessary to uniquely identify a device, [[Page2604]] what other information (if any) should be part of a UDI system database or otherwise linked to the UDIs?

- **Alcon Response:**
  - In keeping with the intent for this to be a repository of product data information, the following information would be useful for the UDI database:
    a. UDI code (Product Data only)
    b. Device Name / Brand name
    c. Device Make / Model / Size
    d. Manufacturer Catalog Number
    e. GMDN / UMDNS Number
    f. Cross-Reference Table listing all the packaging level UDI's for this device, and the associated Unit of Measures for each of those packaging levels
       e.g., Device 123
       0123 = Each
       1123 = Box of 12 Eaches
       2123 = Case of 144 Eaches
    g. Single Use / Reusable flag
    h. Sterile Y/N flag
    i. MRI Compatible Y/N flag

c. If variable data (such as a lot or serial number) is necessary to uniquely identify a device, should such data be included in a UDI system database?

- **Alcon Response:**
  - Variable data = Production Data.
  - The UDI database is intended to be a repository of Product Data.
  - Tracking of variable Production Data is out of scope for this database design.

Section C: Questions Pertaining to Possible Impacts of a UDI System

1. What is the magnitude of the problem to be addressed by the establishment of a UDI system?

Please describe and provide qualitative or quantitative evidence of the incidence of deaths, injuries and illnesses associated with medical devices. What role would a UDI system play in helping to reduce the incidence of such deaths, injuries, and illnesses and how might the structure of a UDI system facilitate this role?

- **Alcon Response:**
  - In the recent DoD GDSN Pilot work conducted through GS1, problems were identified related to device Product Data synchronization, such as:
    a. Trading partners each carrying a different part number for a single item
    b. Product Data records for a single device differ in level of detail and accuracy of the included information across trading partners
    c. Part numbers assigned by non-manufacturing trading partners do not always use globally unique schemes (use of internal-only schemes)
    d. There are limited cross-references of internal-use part numbers to the manufacturer part number in trading partner systems
  - This complicates the ability to find and report on a single device throughout the extended supply and treatment chain.
  - It is unclear if the data to be carried in the proposed UDI database would contribute in any meaningful way to improving patient safety, but it could potentially lessen administration and overhead costs which could be re-deployed towards more patient-centric uses.

2. Questions for manufacturers

a. Current practices. Describe your current practices for applying standards to medical devices, marking identifiers on medical device labeling and managing medical device identifier data. For example, how do you currently use classification standards such as UNSPSC (United Nations Standard Products Service Code), nomenclature standards such as GMDN (Global Medical Device Nomenclature), and identification standards such as GS1 or HIBCC? What percent of your devices are not currently marked with a standardized identifier? Please describe any plans you have to change these practices in the near future.

- **Alcon Response:**
  - Alcon has been a leader in applying both the HIBCC and GS1 standards for marking of Product Data attributes for over 30 years.
  - We sell 50,000+ medical device items with the following product markings:
    a. Virtually all of our commercial, non-capital medical devices carry a UDI at the Item, Box, and Case levels in a barcode (Product Information).
    b. We also encode in a barcode Production Data (Lot, Expiry, and/or Serial Number as appropriate) for a select set of medical device items
  - In keeping with the general mandate of the EU and other global markets, Alcon is in the planning phases to migrate towards use of GMDN codes for all medical devices. This is an expansion of current implementation of GMDN codes for a select set of medical device items.
    We strongly encourage the Agency to adopt the GMDN scheme for identification of medical devices, and that other or multiple codes be strongly discouraged (i.e.,—FDA should mandate GMDN instead of UMDNS).
  - Alcon has limited usage of UNSPSC codes. We are awaiting clear direction and consensus from customers, regulators, and the industry before additional adoption. If FDA were to mandate a classification scheme, we would prefer that one scheme be mandated as opposed to multiple schemes.

b. Changing current identifiers. If you were to add a UDI or change the presentation of your current identifier, please describe your approximate expected capital and operating costs (including labor) to plan for, implement, and apply a UDI to product labeling. To provide context for your estimate, please explain your expected approach to adding a UDI,

considering the possibility that a UDI might be a static number (e.g., a manufacturer/product code) or that it might include a variable number (e.g., manufacturer/product/lot code).

- **Alcon Response:**
  - If the FDA regulatory position is to allow both the HIBCC and GS1 standards without modification as an acceptable UDI for the Product Data portion, then Alcon is compliant today for a substantial portion of our medical device products.
  - In comparison, if the FDA regulatory position is to create a new standard or disallow the existing HIBCC / GS1 markings, then over 50,000 Alcon products would have to be revised to the new markings, which will take many years to implement at an immense cost--for little to no benefit to partners.
  - If variable Production Data is required beyond current regulatory and industry practices, then every production line in every facility will have to be assessed for conformance, remediation plans developed, capital and software acquired, production lines retrofitted and re-validated, product registrations in other countries + ISO CE Mark dossiers updated, etc. The labor, capital, software, and internal costs may likely exceed $1 million per affected production line with an implementation timeline in excess of 5 years (due to the large number of production lines and the availability of internal/external resources to do the work).
  - We believe that these costs would be similar across other similar-sized medical device manufacturers, based on similar estimates from industry groups such as PhRMA on the drug side of the business.
  - Therefore we would request that FDA give serious consideration to a risk-based, phased-in approach to implementation of any additional Production Data requirements to assure that these high costs are applied to the highest risk products .

c. Encoding variable data. If you were to add a UDI bar code with variable data (such as lot or serial number) to medical device labeling, please describe how you would print the variable bar coded information. For example, do you foresee using on-line label printing, other in-house printing, or contract printers to add a UDI bar code?

- **Alcon Response:**

- Alcon manufactures and distributes a wide array of medical devices, from very low-cost consumable items (sutures, surgical drapes, wound dressings, etc.) to highly sophisticated capital equipment, and everything in-between.
- Given this variety of products, and the vast differences between production lines, we would expect that a mixture of all solutions mentioned in the question would be utilized to mark the medical devices, from manual stickering, to contract packaging, to on-line semi-automated solutions.

d. Production line impacts. Considering your operations, are there products where adding a UDI (human readable or barcode; static or variable) to labeling would not be feasible without major capital investment or overhauling production lines? If so, please describe the products and suggest alternatives or solutions.

- **Alcon Response:**
  - Adding Production Data to those products that currently do not carry this extended information will be very problematic and costly. This is due to the size of the packaging, lack of equipment to apply the UDI Production Data, lack of software to generate, inspect, and record the markings, and the costs to actually implement the changes.
  - As emphasized previously, we believe that a risk-based, phased-in approach should be used to determine which products are marked with UDI in general, and which are marked with Production Data in particular.

e. Small devices and small packages. A UDI could present a challenge for some small packages. What percentage of your product line consists of devices whose small size could make placing a UDI on a label problematic? Of those devices identified, what ``alternative placement'' of the UDI would be feasible? Please explain your reasoning. Please describe the nature of the problems and costs to solve such problems. Please suggest alternatives or solutions.

- **Alcon Response:**
  - As stated previously, we believe that a small percentage of our products will have significant challenges to product marking using current technology.
  - Alternatives include:

a. All products, by regulation, currently carry both Product Data and Production Data in human-readable format—these markings can continue to be used in satisfaction of UDI requirements.
b. Many of the smallest products tend to be dispensed from larger shelf packs, and the shelf packs carry in barcodes the Product Data and in many instances the Production Data as well. The shelf pack can easily be scanned at point of dispensing or issuance to a procedure to capture this information.

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